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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/760,854	01/17/2001	Samuel G. Armato III	200655US20	4576

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EXAMINER	
BHATNAGAR, ANAND P	
ART UNIT	**PAPER NUMBER**
2623	

DATE MAILED: 08/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/760,854	ARMATO ET AL.	
	Examiner	Art Unit	
	Anand Bhatnagar	2623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06/24/04*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *8-10, 25-27, and 42-44* is/are allowed.

6)☒ Claim(s) *1,2,4-7,11,12,14,15,18,19,21-24,28,29,31,32,35,36,38-41,45,46,48 and 49* is/are rejected.

7)☒ Claim(s) *3, 13, 16, 17, 20, 30, 33, 34, 37, 47, 50 and 51* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 January 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Response to Amendment

1. Applicant's amendment filed on 06/24/04 has been entered and made of record.

2. Applicant has amended claims 1-3, 6, 18-20, 23, 35-37, and 40. Currently claims 1-51 are pending.

3. Claim 1 has been amended, as well as claims 18 and 35 being similarly amended, with a new limitation of "performing region growing from another seed point located in a subsequent cross-sectional image to segment the major airway within the subsequent cross-sectional thoracic image." In essence applicant argues, on page 20 1st full paragraph, that the prior art of Giger et al. (U.S. patent 5,881,124) and Vining (U.s. patent 6,272,366) does not teach or suggest the step of performing region as now recited in the claim language of claims 1, 18, and 35. Since this is a new limitation examiner will address this limitation in the rejection below.

Regarding claims 2, 19, and 36 applicant argues that the office action does not give why someone skilled in the art would determine the "center of mass" of a segmented major airway. As explained in the office action the process dilation/growing when performed is usually performed where a seed is placed in the center of the object and region growing taking place outward from this region. The process of dilation/growing, using a seed point, is wherein the seed point is the start of the dilation process and it is grown out one pixel layer at a time until it reaches the boundary/s of the object in question, in this case the colon or the

tracheobronchial airways. In the case of an anatomical structure having a hollow lumen the seed point is generally placed in the center of the lumen, i.e. which is the center of mass of the object.

Applicant's argument (bottom of page 20 to top of page 21), for claim 3, is persuasive and therefore, examiner withdraws the rejection for this claim. Claim 20 and 37 have similar limitations as claim 3, therefore the rejections to these claims are also withdrawn.

Regarding claims 6, 23, and 40: Applicant argues (bottom of page 21 to bottom of page 22) that the prior art of Giger et al. does not disclose to identify the fusion of the, identify the cleft point on the lung contour, etc. based on gray level values and applicant also argues that the examiner is using hindsight to construct applicant's instant invention. Examiner disagrees. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Examiner is not using hindsight since the prior art of Giger et al. discloses to obtain the boundaries of the lungs, i.e. read as all the boundaries that compose the lungs (including the cleft point, anterior junction line, and fusion

of the lungs) as well as the thoracic boundaries using gray scale levels (Giger et al.; fig. 1, col. 3 lines 50-67, and col. 4 lines 41-50). Giger et al. discloses to determine the boundaries of the lungs and the thorax in order to determine the presence of an abnormal pathology, such as a nodule, and this is the same motivation why one would look at other regions, i.e. contours of the lung/features of the lungs, which is to diagnose or to rule out other possible pathologies. For example, the costophrenic angles of the lungs are identified in medical images in order to diagnose/rule out the possibility of pneumonia.

Regarding claims 12, 29, and 46: Applicant argues (page 23) that no motivation is given for why the diaphragm would have been identified. Giger et al. discloses to determine/identify the boundaries of the lungs and the thorax. The diaphragm is the lowest most boundary of the thorax and just below the lungs, i.e. the diaphragm is identified since the thoracic boundaries are determined. Further Giger et al. discloses to extract/ remove a specific boundary, i.e. the exam table boundary, from an image (Giger et al.; col. 4 lines 31-35). One in the art could have modified the system wherein after the determination of boundaries the system can remove/extract any boundaries, such as the diaphragm, in order to isolate the lung regions, to enhance the image in a specific region so that a specific boundary is not interfering with the analysis of a specific region, etc.

Regarding claims 8, 25, and 42: Applicant's arguments (pages 23-25) are persuasive and the rejection to these claims are withdrawn. Examiner refers to the rejection below.

DETAILED ACTION

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 11, 28, and 45 rejected under 35 U.S.C. 102(b) as being anticipated by Armato III et al. ("Automated detection of pulmonary nodules in helical computed tomography images of the thorax;" Samuel G. Armato III, Maryellen L. Giger, Catherine J. Moran, Heber MacMahon, and Konio Doi; Department of Radiology, The Uniiversity of Chicago, IL 60637; SPIE Conference on Image Processing, SanDiego, CA.; February 1998; SPIE Vol. 3338.0277-786X/98; pages 916-919).

Regarding claims 11, 28, and 45: A method for the automated segmentation of lung regions in thoracic images, comprising:

acquiring image data representative of plural cross-sectional thoracic images (abstract, section 2 second paragraph, and fig. 1) and ;

generating initial lung contours to segment the lung regions in the plural cross-sectional thoracic images abstract, section 2 second and third paragraphs, and fig. 1), and

refining the lung contours by applying a three-dimensional rolling ball filter to the initial lung contours in the plural cross-sectional thoracic images abstract, section 2 last paragraph on page 917 to top of page 918, and figs 2 and 3, wherein the rolling ball filter is applied to identify lung border indentations followed by interpolation of the indentations of the lung borders, i.e. refining/smoothing the lung borders).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2, 4-7, 12, 14, 15, 18, 19, 21-24, 29, 31, 32, 35, 36, 38-41, 46, 48, and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Giger et al. (U.S. patent 5,881,124) and Vining (U.S. patent 6,272,366 B1).

Regarding claims 1, 18, and 35: Giger et al. discloses a method for the automated segmentation of lung regions in thoracic images (Giger et al.; fig. 1 and col. 1 lines 7-11) comprising:

acquiring image data representative of a cross-sectional thoracic image (Giger et al.; figs. 1 and 2A and col. 3 lines 66 and 67, and col. 4 lines 1-3);

segmenting the lung regions (Giger et al.; fig. 1 and col. 3 lines 55-58).

Giger et al. discloses to obtain a cross-sectional image of the thorax from which the lung boundaries are detected. Giger et al. does not teach to establish a seed in a major airway and to grow from the seed point to extract the major airway. Vining teaches to grow from the seed point and to grow the region of a selected organ in order to extract/isolate this specific organ as a region of interest, such as the tracheobronchial airways (Vining; fig. 15 and col. 3 lines 5-10, 23-30, and 54-56). It would have been obvious to one skilled in the art to combine the teaching of Vining to that of Giger et al. because they are analogous in obtaining and processing images of anatomical structures to analyze these regions for presence of a pathological abnormality. One in the art would have been motivated to incorporate the teaching of Vining into the system of Giger et al. in order to have a reliable efficient method for examining the tracheobronchial and/or colon of a patient to detect early cancer (Vining; col. 2 lines 13-15).

Giger et al. discloses to identify regions/boundaries of the lungs and the thorax. Giger et al. does not teach the feature of "performing region growing from another seed point located in a subsequent cross-sectional thoracic image to segment the major airway within the subsequent cross-sectional thoracic image." Vining teaches the step of region growing using a seed point in a part of a region of an organ in an image (Vining; fig. 15 and col. 3 lines 5-10, 23-30, and 54-56, wherein the organ is the colon or tracheobronchial airway). It would have been obvious to one skilled in the art to combine the teaching of Vining to that of Giger et al. because they are analogous in obtaining and processing images of

anatomical structures to analyze these regions for presence of a pathological abnormality. One in the art would have been motivated to incorporate the teaching of Vining, modified for a second/third/fourth/etc. region seeding and growing in any image or all the images obtained of the organ of interest or within the same image itself, into the system of Giger et al. in order to have a reliable efficient method for examining/extracting the tracheobronchial and/or colon of a patient to detect early cancer (Vining; col. 2 lines 13-15).

Regarding claims 2, 19, and 36: The method further comprising:

determining a first pixel corresponding to a center of mass of the segmented major airway (Vining; col. 3 lines 23-30, wherein the seed point is planted inside the lumen of the organ. It is obvious to one skilled in the art for a dilation process in image processing using a seed point is usually performed wherein the seed point is placed in the center of the region of interest.).

Regarding claims 4, 21, and 38: The method wherein the major airway is the trachea (Vining; col. 3 lines 53-56). The obvious and motivation are the same as claim 1 above.

Regarding claims 5, 22, and 39. The method wherein the major airway is one of the first main stem bronchus and the second main stem bronchus (Vining; col. 3 lines 53-56). The obvious and motivation are the same as claim 1 above.

Regarding claims 6, 23, and 40: A method for the automated segmentation of lung regions in thoracic images (Giger et al.; fig. 1 and col. 1 lines 7-11), comprising:

generating at least one lung contour to segment the lung regions a cross-sectional thoracic image (Giger et al.; fig. 1 and col.3 lines 53-60 where the thorax and lung boundaries are detected).

Giger et al. discloses to obtain images of the thorax containing the lungs wherein a gray scale analysis is performed on the images in order to detect any pathological abnormalities that may be present (col. 3 lines 53-63). Giger et al. obtains multiple computed tomographic images of the lungs. Giger does not discloses to analyze the images for specific anatomical locations in the images, such as the fusion of the lungs, the cleft point, the anterior junction line, etc. It would have been obvious to one skilled in the art to modify the system so that any number of anatomical points of the lungs (such as the cleft, the costophrenic angle, anterior junction line, the points where the lungs are fused together, etc.) as well as any neighboring anatomical structures (such as the diaphragm, heart, esophagus, etc.) may be analyzed using the gray scale of the images, taken into consideration into the data of the image, or suppressed/extracted from the image to enhance the region of interest in the images.

Regarding claims 7, 24, and 41: It is rejected for the same reason as claim 6, 23, and 40 above and for the following limitation of: identifying, within each row of pixels that includes a pixel of the line segment with the highest average gray level value, a pixel with the highest gray level within a predetermined distance of the line segment with the highest average gray level value; and

including within the anterior junction line the pixels identified as having the highest gray level in each row.

It is obvious to one skilled in the art that once the gray scale of all the images are obtained then this data can be analyzed for pixel intensities and their respective locations (the x-y positions, which is equivalent to the row and columns) in each image.

Regarding claims 12, 14, 15, 29, 31, 32, 46, 48 and 49: They are rejected for the same reasons as claims 1, 18, and 35 and claims 6,23, and 40 combined.

Regarding claims 35, 36, 38-41, 46, 48, and 49: For the limitation of a computer readable medium (col. 12 lines 32-34).

Allowable Subject Matter

6. Claims 8-10, 25-27, and 42-44 are allowed.

7. Claims 3, 13, 16, 17, 20, 30, 33, 34, 37, 47, 50, and 51 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

8. Armato III et al. ("Three-dimensional approach to lung nodule detection in helical Ct;" Samuel G. Armato III, Maryellen L. Giger, James T. Blackburn, Kunio Doi, and Heber MacMahon; Department of Radiology, The Uniiversity of

Chicago, IL 60637; SPIE Conference on Image Processing, SanDiego, CA.; February 1999; SPIE Vol. 3661.0277-786X/99; pages 553-559).

Contact Information

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anand Bhatnagar whose telephone number is (703) 306-5914, whose supervisor is Amelia Au whose number is 703-308-6604, group fax is 703-872-9306, and Tech center 2600 customer service office number is 703-306-0377.

SAMIR AHMED
PRIMARY EXAMINER

AB

Anand Bhatnagar

Art Unit 2623

August 25, 2005